



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Douglas A. Treco et al.  
 Serial No. : 09/225,718  
 Filed : January 6, 1999  
 Title : TRANSKARYOTIC PRODUCTION AND DELIVERY OF DNASE

Art Unit : 1636  
 Examiner : J. Ketter

Commissioner for Patents  
 Washington, D.C. 20231

COMMUNICATION TO EXAMINER

The assignee of the application referenced above, Transkaryotic Therapies, Inc. (TKT), is involved in Civil Action No. 97-10814-WGY, filed in the United States District Court of Massachusetts. None of the patents at issue in the litigation is assigned to TKT. Because of this, applicants do not believe that the existence of the litigation is material to the present case. Nor do applicants believe there is an obligation to bring the existence of the litigation to the attention of the Examiner (MPEP § 2001.06(b)). Nonetheless, applicants are making known to the Examiner the existence of this litigation and certain non-confidential documents filed in the litigation.

The history of the litigation is as follows.

On April 15, 1997, Amgen, Inc. filed a Complaint, Summons, and Civil Cover Sheet alleging infringement by TKT of Amgen's U.S. Patent Nos. 5,547,933, 5,618,698, and 5,621,080.

On April 15, 1998, the Court issued a Memorandum and Order, wherein the Court determined that all of TKT's allegedly infringing activities to this date fall within the Section 271(e)(1) exemption, granted defendants' Motion for Summary Judgment of Noninfringement, denied all remaining motions, and administratively closed the matter.

## CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

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Usa G. Gray  
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On June 9, 1999, TKT filed Defendant's Motion to Reopen Amgen's Action for Declaratory Judgment and a Memorandum in support of that motion.

On June 10, 1999, a Notice was entered endorsing the Order Granting Motion to Reopen Case for Declaratory Judgment. Amgen amended the Complaint on October 7, 1999 to allege infringement of two additional patents, U.S. Patent Nos. 5,756,349 and 5,955,422.

TKT submits for the Examiner's review the following non-confidential portions of documents filed in the Civil Action that may be of relevance in the present case because they relate to Amgen's belief regarding patentability of TKT's gene activation technology (certain portions relating to TKT's manufacturing processes have been redacted). For example, Opinion No. 5 in Dr. Richard Kolodner's Expert Report discusses Amgen's belief regarding patentability of TKT's gene activation technology. The documents submitted are: Amgen's Amended Complaint filed October 7, 1999; TKT's corresponding Amended Answer; Dr. Richard D. Kolodner's Expert Report (30 pages) with accompanying exhibits; sections of the transcript of the March 8, 2000, Deposition of Thea D. Tlsty, Ph.D.; sections of the transcript of the February 9, 2000, Deposition of Richard D. Kolodner, Ph.D.; sections of the transcript of the February 10, 2000, Deposition of Richard D. Kolodner, Ph.D.; and sections of the transcript of the February 22, 2000, Deposition of Harvey F. Lodish, Ph.D. The references cited in these documents are disclosed in the Information Disclosure Statement that accompanies this communication.

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Attorney's Docket No.: 07236-013004 / DNASE Div. Cont.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

5/19/00

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